

MAY - 4 2012

510(k) Summary
Quantum BioEngineering, Ltd.
Quantum™ Dental Implant System
K112279

May 1, 2012

ADMINISTRATIVE INFORMATION

Manufacturer Name: Quantum BioEngineering, Ltd.
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name: Quantum™ Dental Implant System
Common Name: Dental Implant and abutment
Classification Name: Implant, endosseous, root form
Endosseous dental implant abutment

Classification Regulations: Class II, 21 CFR 872.3640

Product Code: DZE, NHA

Classification Panel: Dental Products Panel
Reviewing Branch: Dental Devices Branch

INTENDED USE

Quantum™ Dental Implant System implants are intended for immediate or delayed placement in the bone of the maxillary or mandibular arch. Quantum Dental Implant System abutments are intended for use as support for crowns, bridges or overdentures. When a one-stage surgical approach is applied, threaded implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate. When using the push-in technique for fin-type or threaded implants, delayed loading is required.

DEVICE DESCRIPTION

The Quantum Dental Implant System includes root form, endosseous dental implants with internal Morse taper and external hex abutment interfaces. The implants are made of titanium alloy with three surface options (RBM, acid etch, HA coated), and are provided in both threaded and a grooved (fin-type) designs. There are four sizes of the diameter of the internal Morse taper (implant well), designated as the 2.0, 2.5, 2.75, and 3.0 Series. For all series, the threaded and fin-type implant designs are each provided in the following sizes: diameters of 4.5, 5.0, 5.5, and 6.0 mm, with each diameter in lengths of 5, 6, 9, 11, and 14 mm. The 2.0 Series of the threaded and fin-type implant designs also include: 4.0 mm diameter in 5 and 6 mm lengths, 8.0 mm diameter implants in 5 and 14 mm lengths, and 5.0 mm diameter available only in lengths of 5 and 6 mm. The 2.5 Series of the threaded and fin-type implant designs also include 4.0 mm diameter in lengths of 5, 6, 9, 11, and 14 mm.

Abutments for cement-retained prostheses are provided for each diameter implant. All abutments are made of titanium alloy. Abutments with a Morse taper interface are provided for all implant series in straight, 15° and 25° angled designs. The 2.0 Series Morse taper abutments are provided in 5 mm and 7 mm platforms; all other Series are provided in 3.5, 4, and 5 mm platforms. External hex interface abutments are provided for the 2.5, 2.75, and 3.0 Series implants in straight, 15° and 25° angled designs. The 2.5 Series hex abutments are 4 mm platform; the 2.75 and 3.0 Series hex abutments are 4.5 mm platform. Healing plugs are provided for each implant series in titanium alloy and polyethylene.

EQUIVALENCE TO MARKETING DEVICE

The Quantum Dental Implant System is substantially equivalent in indications and design principles to the following predicate devices:

- Quantum BioEngineering, Ltd., Components of the Quantum™ Versatility Dental Implant System, cleared under K011223,
- Quantum BioEngineering, Ltd., Quantum™ Versatility Dental Implant System, cleared under K002241,
- Quantum BioEngineering, Ltd., Quantum Versatility™ Implant System, cleared under K991250,
- Bicon, LLC., Bicon Implants with a 2.5mm Internal Connection, cleared under K092035,
- Bicon, Inc., 4.5 x 6.0mm and 6.0 x 6.0mm Dental Implant, cleared under K050712,
- Bicon, Inc., 6.0 x 5.7mm Dental Implant, cleared under K010185, and
- Astra Tech AB, Astra Tech Implant System, cleared under K101732.

The subject device and the predicate devices have the same intended use and have the same technological characteristics. The subject device and the predicate devices also encompass the same range of physical dimensions for both the implants (diameter and length) and abutments (diameter, height, and angulation). The subject device implant and abutment designs, materials, and surfaces are the same as the predicates K011223, K002241 and K991250. The subject device implant largest diameter and shortest lengths are the same as the predicates K092035, K050712, K010185 and K101732.

The subject and predicate devices are packaged in similar materials and sterilized using similar methods, or provided nonsterile to be sterilized using similar methods.

Non-clinical testing data that was provided or referenced to demonstrate substantial equivalence included detailed engineering analysis, dimensional analysis, surface area and bone-to-implant contact area analysis, and static and dynamic compression-bending testing according to ISO 14801.

Any differences in the technological characteristics between the subject device and the predicate devices do not raise new issues of safety or efficacy.

Overall, the Quantum Dental Implant System has the following similarities to the predicate devices:

- has the same intended use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and
- has similar packaging and is sterilized using the same materials and processes



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Quantum BioEngineering, Ltd.
C/O Ms. Linda K. Schulz
Consultant
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11234 El Camino Real, Suite 200
San Diego, California 92130

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Re: K112279
Trade/Device Name: Quantum™ Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: May 1, 2012
Received: May 2, 2012

Dear Ms. Schulz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

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Device Name: Quantum™ Dental Implant System

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Prescription Use X
(Part 21 CFR 801 Subpart D)


AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1


(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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